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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,753	10/29/2001	Yasuhiro Sakai	3029-74	7298
7590 01/13/2004				
Lance J. Lieberman, Esq. Cohen, Pontani, Lieberman & Pavane 551 Fifth Avenue, Suite 1210 New York, NY 10176			EXAMINER PRATS, FRANCISCO CHANDLER	
			ART UNIT 1651	PAPER NUMBER

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/005,753

Applicant(s)

SAKAI ET AL.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

The amendment filed October 27, 2003, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 27 and 28 have been added.

Claims 1-28 are pending.

Response to Amendment

The amendment to the claims filed on October 27, 2003, does not comply with the requirements of 37 CFR 1.121(c) because the claim listing does not list all pending claims, nor the status of all pending claims. On page 4 of the response of October 27, 2003, applicant indicates that claims 1-26 are pending. However, the claim listing does not contain claims 1-19 or their status. Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states (emphasis added) :

(c) *Claims*. Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the

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application. *In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).*

(1) *Claim listing.* All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (e.g., Claims 1-5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn-currently amended."

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, i.e., without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, i.e., without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*

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(i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

Technically, failure to present a proper claim listing can render the current submission non-responsive. However, the claims will be examined on the merits in the interests of compact prosecution. Lastly, note that applicant's statement on page 4 of the response of October 27, 2003, fails to state that new claims 27 and 28 are also pending.

Election/Restrictions

Applicant's election of the group II invention, claims 20-23, the species wherein the nitrite reducer is sulfamic acid, in Paper No. 5, filed June 9, 2003, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

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As discussed immediately above, election was made **without** traverse in Paper No. 5, filed June 9, 2003.

It is noted that applicant did not originally present claims directed to a staining reagent. Rather applicant originally presented claims directed to a stain diluent, a different product having a combination of ingredients different than the combination presently recited in the claims as amended. This presentation of a new and different product could be considered non-responsive, since applicant has switched their invention to one which was not originally presented. However, in the interests of compact prosecution claims 20-28 will be examined on the merits

Claims 20-28 are examined on the merits to the extent they read on the elected species.

Claim Rejections - 35 USC § 102

Claims 20, 21 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Jackson (U.S. Pat. 5,668,011).

Jackson '011 describes a test kit for determining the presence of *Helicobacter pylori* using urease as a marker enzyme. The described kit contains bromophenol blue dye, Tris buffer and sulfamic acid, the elected species of nitrite reducing

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substance. See column 2, lines 18-32. Thus, Jackson '011 discloses a composition comprising all of the claimed ingredients, including the elected species of nitrite reducing reagent. A holding of anticipation over claims 20 and 21 is therefore required. Moreover, because the prior art reagent contains all of the claimed ingredients and can be maintained at the claimed pH, it necessarily can be put to the intended use recited in claim 25.

Claim Rejections - 35 USC § 103

Claims 20, 21, 24, 25, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (U.S. Pat. 5,668,011).

As discussed above, Jackson '011 describes a test kit for determining the presence of *Helicobacter pylori* using urease as a marker enzyme. As also discussed above, the described kit contains bromophenol blue dye, Tris buffer and sulfamic acid, the elected species of nitrite reducing substance. Jackson '011 differs from the claims in that, although it can be used to maintain the claimed pH, the buffer used in the kit described by Jackson '011, Tris, has a higher pKa than that recited in claim 24. However, the selection of a suitable buffer for use in the reagent described by Jackson '011 clearly would have been a

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matter of routine optimization on the part of the artisan of ordinary skill at the time of applicant's invention. One of ordinary skill in the art of enzyme assays such as disclosed in Jackson '011 clearly knew how to test different known buffers to determine their suitability for use in said assays. Similarly, with respect to the dyes recited in new claims 27 and 28, one of ordinary skill at the time of applicant's invention clearly would have known how to determine through routine experimentation which known dyes would be suitable the reagent described by Jackson '011. Absent some demonstration that the claimed dyes and buffers impart unexpected properties to the claimed composition, a holding of obviousness is clearly required.

Claims 20-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (U.S. Pat. 5,668,011) as applied to claims 20, 21, 24, 25, 27 and 28 above, and in further view of Jackson (U.S. Pat. 5,439,801).

As discussed above, Jackson '011 renders obvious claims 20, 21, 24, 25, 27 and 28 because those claims recite the use of known buffers and dyes in a buffer-containing and dye-containing composition, the selection of suitable buffers and dyes being routine in the art of colorimetric enzymatic assays. Claims 22,

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23 and 26 differ from Jackson '011 in the use of an additional ingredient, a cationic surfactant.

However, Jackson '801 clearly discloses that urease-based assays for *H. pylori* can be significantly improved by adding a surfactant thereto, because the detergent releases the urease enzyme from the cell wall. See column 6, line 66, through column 7, line 10. Thus, the artisan of ordinary skill clearly would have been motivated by the disclosed advantages of using a surfactant in a urease-based *H. pylori* assay, such as that described by Jackson '011, to have added a surfactant to reagents used in said assays. It is noted that the surfactant of Jackson '801 is not one of the cationic surfactants recited in applicant's claims. However, in view of the clear disclosure by Jackson '801 that surfactants are desirable in urease-based *H. pylori* assays, the selection of suitable surfactants would have been considered to have been well within the purview of the artisan of ordinary skill conducting routine testing. Therefore, absent some demonstration of an unexpected result coming from the use of the claimed ingredients, a holding of obviousness is clearly required.

No claims are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can

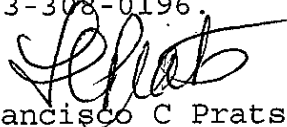
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be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Francisco C Prats
Primary Examiner
Art Unit 1651

FCP